DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-06

October 18, 2002

Mr. Christopher A. Bohlman
President and Owner
Unico Holdings, Inc.
1830 2nd Ave. N
Lake Worth, FL 33461-4202

Dear Mr. Bohlman:

During an inspection of your over-the-counter drug manufacturing facility located at the above address on June 24-July 8, 2002, Investigators Minerva Rogers and Ana del P. Cintron documented deviations from the Current Good Manufacturing Practice (GMP) regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). Failure to conform to GMP causes products manufactured by your firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Investigators Rogers and Cintron found the following deviations from GMP:

1. Failure to establish adequate control procedures for process validation, in that:

   (a.) Revalidation protocols do not cover the largest batch size or the most complex manufacturing process;
   (b.) Revalidation protocols establish limits (i.e., batch temperature) for a parameter that is not monitored during actual production;;
   (c.) Batches are manufactured between validation runs and are distributed before validation is complete; and,
   (d.) Validation includes conformance to the appropriate USP monograph, but all the required monograph tests are not performed [21 CFR 211.110].

2. Discrepancies and failure to meet specifications are not thoroughly reviewed, in that no effort is made to determine the reason for out-of-specification test results; nor are label discrepancies explained [21 CFR 211.165].

3. Actual and percentage of theoretical yields not always determined, in that yields are calculated for combined batches, not based on actual amount of product packaged [21 CFR 211.103].

4. Labeling control inadequate, in that there is no written procedure for label reconciliation, nor are labels proofread prior to release [21 CFR 211.125].

5. All drug components are not weighed or measured, nor are weights of partial bags listed on the containers [21 CFR 211.101].

6. There is no procedure or documentation demonstrating when particulate filters used in the manufacture of oral electrolyte solutions are changed nor is there a record showing the name or initials of who performed this task [21 CFR 211.68].

7. Drug product samples are not adequate or representative of the entire batch, in that a single sample taken from the top of the mixing tank is used to determine uniformity of blend and final chemistry testing [21 CFR 211.110].

8. Laboratory records do not always include raw data for all the laboratory testing performed [21 CFR 211.194].

We are in receipt of your response to the List of Observations left at your firm at the close of the inspection. The corrections listed will be verified at our next inspection. However, we do have questions about several of your responses:

Your response questions the use of three consecutive runs in validation procedures. The purpose of process validation procedures is to assure both you and FDA that the process will yield consistent results. The validation process is supposed to take place prior to the distribution of any product using that process. Yet our investigators found that batches made in between the validation runs were distributed prior to completion of the validation procedures.

In answer to observations made about not performing specific gravity testing as required by the covering monograph, your response states your belief that under certain circumstances not every analytical procedure listed in an article's monograph needs to be performed, but offers no documentation or historical data to support your belief. Further, our investigators found that the computer program used by your firm to calculate the percentage of theoretical yield bases this calculation on the specific gravity of the batch, a test which, by your own admission, is not performed. Please submit any documentation you may have supporting the calculations of this computer program.

Your response indicates that label discrepancies were due to coded unlabeled bottles that were packaged in bulk for a particular customer, yet our investigators found no labeling agreement that would cover the interstate shipment of unlabeled bottles. Please provide us with an explanation regarding the shipment of unlabeled bottles.

Your response to Observation #10 does not address FDA's concerns. The records associated with a batch should be a complete history of that batch, with all records reconciled and all discrepancies explained. The number of "twins" or "triples" should be accounted for as part of the reconciliation.

Your responses to Observations 15 and 25 also do not address the issue. Our investigators found that your firm does not routinely weigh each bag of ingredients going into a batch, although the batch records seem to indicate that every bag is weighed. Please explain.

The violations identified above are not intended to be an all-inclusive list of deficiencies at your facility. Please review the List of Observations left at your firm along with your response and our comments above. It is your responsibility to ensure that all products manufactured by your firm are in compliance with the Act and with the GMP regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct any deviations that remain and to provide documentation of corrective actions already taken. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct all the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations, and to respond to the questions raised in this letter. If corrective action has not been completed, please provide a timetable within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Martin E. Katz, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751, or you may call (407) 475-4729.

Sincerely,

Kendall W. Hester

for Emma R. Singleton
Director, Florida District